# NMRU Report 2021

This report covers the period January to December 2021 and includes the activities of the NMRU that provides microbiology confirmatory and reference testing for SNBTS P&T, TCAT, Clinical Laboratories, Advanced Therapeutics, NIBTS and other external customers.

**Achievements**

- Supporting the convalescent plasma programme until closure, testing of TCAT samples and post donation alerts for SARS-CoV-2 RNA
- Collaboration in PHS SARS-CoV-2 seroprevalence study to advise Scottish Government
- Development of new procedures and processes for implementation of anti-HBc screening, confirmation and lookback
- Evaluation of a range of microbiology assays to provide resilience (as manufacturers either withdraw or notify that assays will not be taken forward for UKCA marking)
- Achievement of above whilst no reduction in BAU activities and with additional pressures of social distancing etc.

**Key challenges identified for NMRU to progress over the next five years**

- Transition to IT systems to support NMRU to provide electronic test requesting, resulting and archiving (currently manual systems).
- Ensuring NMRU retains ability to perform quality confirmations that comply with *in vitro* diagnostic devices regulations.
- Discontinuation of many low throughput assays used in NMRU as manufacturers decide to remove assays from market rather than take through CE to UKCA marking process.

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| **Workload** | In total 4343 samples were referred to the NMRU in 2021. Samples referred to NMRU for confirmatory testing each follow a specific confirmatory algorithm that may require up to eight different tests to conclude. NMRU also receives additional referrals for screening (stem cells donors, tissue donors, islet cell donors, screening test failures, short samples, clinical trial samples). Serological testing of SARS-CoV-2 antibody levels for convalescent plasma ceased in March 2021. Therefore, after the large increase seen in 2020, referral numbers returned to levels nearer normal, although still higher than the five-year period (2015-2019) prior to the pandemic (range=3479-4047 referrals) (seen NMRU Annual Report 2020 supplementary data). |
| **KPIs** | Turnaround is in calendar days (including Saturday, Sundays and public holidays) from receipt of sample to completion of test report - entry on eProgesa/Tissuetrace). Turnaround times increased for all markers in 2021. This is likely to be due to the increased workload, SARS-CoV-2 referrals, working restrictions due to the pandemic delaying result input into donor databases and specifically for HBV, the batching of confirmatory HBsAg testing on the Alinity s platform. |
| **Turnaround Times** | The mean turnaround time increased and percentage of reports issued within 14 days decreased for all mandatory markers (except for HEV). |

| Specificity | Turnaround time (days) | Turnaround time – confirmed positive (days) | Percentage reported within 14 days (%) |
|---|---|---|---|
| HBV | 9.9 | n/a | 78.9 |
| HCV | 8.4 | 3.0 | 83.9 |
| HIV | 8.1 | n/a | 90.6 |
| Syphilis | 6.5 | 5.6 | 96.0 |
| HTLV | 9.4 | n/a | 82.9 |
| HEV | 3.1 | 3.1 | 100.0 |

**Malaria referral/screens**

| Referral location | Turnaround time (days)* | Turnaround time – confirmed positive (days)* | Percentage reported within 14 days (%)* |
|---|---|---|---|
| Tissue Services | 6.6 | n/a | 94.3 |
| NIBTS | 6.5 | n/a | 93.3 |
| SNBTS donor referrals | 24.4 | n/a | 19.7 |

Malaria confirmatory testing (PCR) is performed by NHSBT Microbiology Services Laboratory and turnaround times are therefore out with NMRU control if malaria PCR is required.

## MHRA Inspections

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| Edinburgh JCC | 14-16 September 2022.<br>No comments specific to NMRU |

## EQA

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| Molecular (no. of distributions) | NEQAS: HCV RNA (2), NEQAS HEV RNA (3), SARS CoV-2 RNA (11)<br>EDQM: HBV, HCV, HIV NAT (1)<br>QCMD: HBV DNA (2), HCV RNA (2), HIV RNA (2), HEV RNA (1), WNV RNA (1), CMV DNA (2), SARS-CoV-2 (2)<br>**All schemes satisfactory.** |
| Serology (no. of distributions) | NEQAS: Blood Borne Viruses (6), Blood Donor Screen (6) Hepatitis B Serology (3), anti-HBs (3), anti-HCV (3), anti-HIV 1& 2 (3), Syphilis antibodies (2), HEV (2), *T.cruzi* (1), malaria (1)<br>**All schemes satisfactory.** |

## National Policies

Polices updated in 2021 by NMRU staff

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| NATP DON 016 | SNBTS policy for testing of blood, tissue, cell, gametes, organ donors and allogeneic starting material for ATMPs for mandatory and additional microbiological markers |
| NATP QUAL 019 | Recall of products and components prepared from donors with Microbiology Repeat - Reactive Test Results |

## Change controls, risk assessments & validations

Change controls (with associated risk assessments and validations) approved in 2021 to support developments within the NMRU.

| Document Type | Document Number | Document Title | Active Date |
|---|---|---|---|
| Change Controls | CC1267 | Upgrade of the stand-alone laptop associated with the Qiagen Rotor-Gene realtime thermal cycler A1116 to Microsoft Windows 10 | 09/02/2021 |
| | CC1698 | Upgrade/replace the stand-alone laptop associated with the Qiagen Rotor-Gene realtime thermal cycler A1147 | 31/03/2021 |
| | CC1706 | The NMRU easyMAG nucleic acid extraction systems (A0184 & A1113) software upgrade | 31/03/2021 |
| | CC1736 | Requalification of LT-4500 microplate readers and associated LT.com software with Windows 10 PC | 12/05/2021 |
| | CC1745 | Replacement of NMRU NAT assays for the detection of HCV RNA, HIV RNA and HBV DNA | 30/08/2021 |
| | CC1835 | Replacement microplate reader for ELISAs required in the NMRU | 11/10/2021 |
| | CC1862 | Validation of the current NMRU CMV NAT assay for testing cellular therapy products for CMV DNA. | 16/11/2021 |
| | CC1871 | Introduction of a confirmatory NAT test for Malaria. | 01/12/2021 |

## Quality Incidents

NMRU logged 26 quality incidents in Qpulse (25 green; 1 amber). 88.5% (23/26) closed out within 45 days (46.2% within 30 days/target date; 12/26).

NMRU Quality Incidents 2021.docx

## NMRU Representation Internal

Microbiology Test Evaluation Group (MTEG)
Infection Control Committee (ICC)
Clinical Safety and Governance Group (CGSG)
Healthcare Scientist Forum (NSS)
JCC Building Users Group
Local & National Change Control Groups
SNBTS L&D Group
COSHH Review Group
Local and National H&S Committees
NSS Safety Working Group
Biological/GM Safety Committee
Waste Management Group (NSS)
JCC Project Group
Operational Managers Group (OMG)
Digital Strategy & IT Demand Delivery Group (DSIDD)

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| **External** | JPAC Standing Advisory Committee Transfusion Transmitted Infections (SACTTI)<br>SACTTI parasite sub-group<br>NHSBT Kit Evaluation group (KEG)<br>NHSBT/PHE Epidemiology Steering Group<br>NHSBT Transfusion Microbiology Clinical Group<br>Strathclyde University BSc in Biomedical Science (BM 328) |
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| **Additional Documents** | • CGSG22.11.14b Donor Infection Surveillance Report (No.23) 2021<br>• CGSG22.11.14d Tissue Infection Surveillance Report (No.18) 2021<br>• CGSG21.05.08 NMRU Quarterly Report (Jan – Mar 2021)<br>• CGSG21.08.09 NMRU Quarterly Report (Apr – Jun 2021)<br>• CGSG21.11.13 NMRU Quarterly Report (Jul – Sep 2021)<br>• CGSG22.02.09 NMRU Quarterly Report (Oct – Dec 2021)<br>  <br>NMRU Annual Report 2021 supple |
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| **Publications** | PALMATEER NE, DICKSON E, FURRIE E, GODBER I, GOLDBERG DJ, GOUSIAS P, JARVIS L, MATHIE L, MAVIN S, MCMENAMIN J, MCNEILLY TN, MURCIA P, MURRAY J, REID G, ROBERTSON C, TEMPLETON K, VON WISSMANN B, WALLACE LA, WAUGH C, MCAULEY A. National population prevalence of antibodies to SARS-CoV-2 in Scotland during the first and second waves of the COVID-19 pandemic. *Public Health.* 2021 Sep;198:102-105.<br><br>RECOVERY Collaborative Group. Convalescent plasma in patients admitted to hospital with COVID-19 (RECOVERY): a randomised controlled, open-label, platform trial. *Lancet.* 2021 May 29;397(10289):2049-2059.<br><br>MCDONALD L, WISE H, MUECKSCH F, POSTON D, MAVIN S, TEMPLETON K, FURRIE E, RICHARDSON C, MCGUIRE J, JARVIS L, MALLOY K, MCAULEY A, PALMATEER N, DICKSON E, HATZIIOANNOU T, BIENIASZ P, JENKS S. Comparison of SARS-CoV-2 serological assays for use in epidemiological surveillance in Scotland. *J Clin Virol Plus*. 2021 Sep;1(3):100028.<br><br>COOPER RS, FRASER AR, SMITH L, BURGOYNE P, IMLACH SN, JARVIS LM, ZAHRA S, TURNER ML, CAMPBELL JDM. Rapid GMP-compliant expansion of SARS-CoV-2-specific T cells from convalescent donors for use as an allogeneic cell therapy for COVID-19. *Frontiers in Immunology*, *section Alloimmunity and Transplantation*. 2021 Jan 8;11 |